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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CLOW, LORI A	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 12/17/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/871,961	SARMA ET AL.	
	Examiner	Art Unit	
	Lori A. Clow, Ph.D.	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09/25/02* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-61* is/are pending in the application.

4a) Of the above claim(s) *44-47,58,60 and 61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-43, 48-57, 59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicants' arguments, filed 25 September 2002, have been fully considered by they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application. Claims 1-34 have been cancelled. New claims 35-61 have been added.

Claims Withdrawn

Newly submitted claims 44-47, 58, 60 and 61 are directed to inventions that are independent or distinct from the invention originally claimed for the following reasons:

Claims 44 and 45 are drawn to kits for diagnosis of aspergillosis, classified in Class 435, 7.1.

Claim 46 is drawn to an isolated antibody, classified in Class 530, subclass 387.1. Methods of diagnosis using polypeptides, which is the elected invention, are different from antibodies that specifically bind to said peptides. They constitute separate chemical entities and would require undue search. Furthermore, polypeptides and antibodies have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examined together as compared to being searched separately.

Claim 47 is drawn to a method for preventing or treating aspergillosis, classified in Class 514, subclass 2. The inventions can be shown to be distinct if either or both of the following can

be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the polypeptides of the elected group can be used in the distinct processes of the invention of treating or preventing aspergillosis or, alternatively, the activity of a protein can be utilized in an industrial process for chemical processing. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Claim 58 is drawn to a method for diagnosing aspergillosis comprising obtaining mast cells from a patient and stimulating them to determine histamine release, classified in Class 435, subclass 325. Diagnosis, in the originally elected claims, was drawn to diagnosis using a body fluid sample bound to an ELSIA and not to isolated mast cells. The inventions are different.

Claim 60 is drawn to a method for producing antibodies, classified in Class 424, subclass 139.1. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the polypeptides of the elected group can be used in the distinct processes of the invention of producing antibodies or, alternatively, the activity of a protein can be utilized in an industrial process for chemical processing. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Claim 61 is drawn to a method for proliferating immune cells classified in Class 435, subclass 70.4. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the polypeptides of the elected group can be used in the distinct processes of the invention of proliferating immune cells by administering peptides of elected invention or, alternatively, the activity of a protein can be utilized in an industrial process for chemical processing. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 44-47, 58, 60 and 61 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

Claims 35-43, 48-57, 59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a

determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) In order to practice the claimed invention one of skill in the art must be able to diagnose aspergillosis based upon the amount of peptide IgG/IgE complexes and correlate absorbance values with acuteness of aspergillosis. For the reasons discussed below, this would constitute undue experimentation and the experimentation would not be routine, as diagnostic ELISA for aspergillosis is not known in the art.

b) The specification provides little or no guidance to enable the practice of said invention. The specification only shows, in Table 2, that synthetic peptides react with sera of aspergillosis patients.

c) Table 2 provides sera absorbance levels in terms of IgE levels and IgG levels in control patients verses aspergillosis patients. However, there is no indication in the specification that numbers corresponding to levels of absorbance are diagnostic. A level of 0.145 in a supposed aspergillosis patient verses a level of 0.09 in a control patient does not provide diagnosis when there are no known parameters in the specification or the prior art that indicate sera levels as being diagnostic. Furthermore, acuteness of disease is supposedly inversely related to sera absorbance levels, however, no concrete levels have been established for diagnosis and there is nothing in the specification or the prior art that would point one in the direction of ascertaining appropriate diagnostic levels.

d) The invention is drawn to methods of diagnosing aspergillosis using ELISA.

e) While the prior art does contain references to ELISA plates as useful to confirm a diagnosis, as in the case of Lyme disease, no comparable methods for aspergillosis confirmation or diagnosis have been established.

f) The skill of those in the art of molecular biology is high, however there is no guidance in the specification that would enable even a skilled practitioner to practice the said invention without undue experimentation in order to test a variety of populations and gather statistically significant data that would allow one to establish appropriate sera absorbance levels that are actually diagnostic of aspergillosis.

g) There is no way a priori of predicting actual diagnostic levels, given no guidance in the prior art.

h) The claims are broad because they are drawn to levels that are not defined in the specification or the prior art. The above specification would lead one to practice undue experimentation in order to practice the said invention, as the values for diagnosis are not disclosed.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (703) 306-5439. The examiner can normally be reached on Monday-Friday from 10am to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Marianne P. Allen

MARIANNE P. ALLEN
PRIMARY EXAMINER
GROUP 1800
AU1631

December 10, 2002

Lori A. Clow, Ph.D.
Art Unit 1631
Lori A. Clow